

Ofterska-Sujkowska G, Jagodzinska-Kalinowska K, Matusiewicz W  
Agency for Health Technology Assessment in Poland (AOTM), Warsaw, Poland

**OBJECTIVES:** To identify what was the influence of cardiovascular drugs recommendations issued by AOTM in years 2005-2012 for the reimbursement decisions taken by Minister of Health (MoH). The main task of AOTM, established in 2005, is to prepare recommendations on financing all medical technologies from public funds for the MoH. For all new health technologies entering market full pharmacoeconomic evaluations are required before the reimbursement decisions are taken by MoH. **METHODS:** Among recommendations of AOTM published until the end of 2012 we analyzed all related to cardiovascular drugs. The recommendations were identified and categorized into types of recommendations (positive or negative). We compared the outcomes with reimbursement list officially published by MoH (January 2013). **RESULTS:** Among 753 documents (recommendations, opinions, statements) issued by AOTM, only 38 (5%) applied to innovative, cardiovascular drugs. AOTM issued positive recommendations for reimbursement to 22 of 38 of cardiovascular drug submissions (58%). 16 of 38 (42%) were not approved and received negative recommendations. Having analyzed the reimbursement list we realized that only 10 of 38 (26%) drugs assessed by AOTM are occurred on the reimbursement list. 9 of 10 drugs (90%) were positive recommended by AOTM. Only 1 drug (10%) was assessed negative. **CONCLUSIONS:** The influence of recommendations issued by AOTM for cardiovascular drugs for reimbursement decisions taken by MoH were not significant with respect to place the drugs on the list. But we can realize that only 1 drug with negative AOTM recommendation exists on the list. The conclusion indicates that the medicine with negative recommendations probably will not be accepted (in 90%) for reimbursement from public sources. Contrarily, not every drug with positive recommendation issued by AOTM will be placed on the reimbursement list.

#### PCV139

##### EVALUATION OF ANTIHYPERTENSIVE DRUGS ON THE REIMBURSEMENT LIST FOR THE DELISTING POLICY IN KOREA

Kim J<sup>1</sup>, Lee HY<sup>1</sup>, Kim CH<sup>2</sup>, Lee S<sup>3</sup>, Lee YS<sup>4</sup>, Sohn HS<sup>5</sup>, Choi SE<sup>1</sup>

<sup>1</sup>Seoul National University, Seoul, South Korea, <sup>2</sup>Inje Institute of Advanced Studies (IIAS), Seoul, South Korea, <sup>3</sup>College of Pharmacy, Suwon, South Korea, <sup>4</sup>Keimyung University, Daegu, South Korea, <sup>5</sup>Sookmyung Women's University, Seoul, South Korea

**OBJECTIVES:** This study was performed to evaluate and provide a new positive list of antihypertensive drugs for reimbursement in the Korean national health insurance. **METHODS:** First, among total 1,226 items, 360 combination items were excluded from this evaluation and 25 essential drug items (ban-on-delisting drugs, orphan drugs, emergency drugs, and drugs without any alternatives) were to remain on reimbursement list without any evaluation. Next, clinical usefulness was evaluated by criteria from medical textbooks, guidelines, and WHO lists, and 1 item was to be delisted due to lack of clinical usefulness. In the third step, daily cost was calculated. Drugs which belong to bottom 25% in daily cost were defined as "relatively low-price drugs," which could remain on the list without subsequent evaluation. Other drugs were to be evaluated by cost-effectiveness. Clinical effectiveness was evaluated based on proxy outcomes (blood pressure) and final outcomes (mortality, morbidity) by reviewing clinical literatures and 6 assessment reports from overseas health technology institutions as well as opinions of clinical experts. **RESULTS:** There was no clear evidence depicting differences in clinical effectiveness. Therefore, the prices of hypertension drugs would have to be reduced to the lowest level of all hypertension drugs if a cost-minimization principle is applied. However, the lowest levels within each class were suggested instead in recognition of differences in adverse events and effects on co-morbidity among the classes. **CONCLUSIONS:** It was not proven that a particular class or ingredient among hypertensive drugs was superior to others. However, the policy based on this result has to be carefully implemented. It is important that practicability, fairness, and equity of the result as well as scientific accuracy have to be balanced since this type of study is commonly associated with interests of stakeholders.

#### PCV140

##### COMPARATIVE EFFECTIVENESS RESEARCH ON THE NEW ANTICOAGULANTS- IS IT WORTH IT?

Wisloff T, Hagen G

NOKC, Oslo, Norway

**OBJECTIVES:** To investigate whether or not elimination of decision uncertainty related to the new anticoagulants would be cost-effective, by calculating the added value of conducting an RCT comparing the new oral anticoagulants (apixaban, dabigatran and rivaroxaban) relative to each other and relative to warfarin for stroke prevention in patients with atrial fibrillation. **METHODS:** We developed a decision analytic model, designed as a probabilistic Markov model containing 200 different probability distributions. The model included eight health states; atrial fibrillation (AF), heart failure, moderate stroke sequela, severe stroke sequela, atrial fibrillation with previous acute myocardial infarction (AMI), atrial fibrillation with previous stroke, major gastrointestinal bleeding and dead. Epidemiological input data was gathered from registries. Data on Quality of Life were based on published EQ-5D data and costs were based on national tariffs. Efficacy data included the three major randomised controlled trials comparing each of the new oral anticoagulants (apixaban, dabigatran and rivaroxaban) to warfarin. Current efficacy estimates indicate that the new anticoagulants are efficacious on some, but not all, outcomes compared to warfarin. However, no direct evidence comparing any of these new anticoagulants with each other is yet available. **RESULTS:** Expected value of perfect information analysis on groups of parameters (EVPI) for efficacy parameters was clearly much higher than EVPI for other parameters (QALYs, costs and baseline risk epidemiological data). Population EVPI for efficacy data

was \$ 1.3 billion in a population of 5 million, given an assumed threshold value of \$ 100,000 per QALY gained. **CONCLUSIONS:** There is clearly an added value in conducting more research on the efficacy of new oral anticoagulants. Hence, new randomized controlled trial(s) comparing all of the new oral anticoagulants would probably decrease decision uncertainty considerably.

#### PCV141

##### DEMOGRAPHIC AND CLINICAL CHARACTERISTICS, AND TREATMENT OF CARDIOVASCULAR RISK FACTORS AMONG U.S. ELDERLY PATIENTS WITH HIGH-RISK VASCULAR DISEASE

Zhao Z<sup>1</sup>, Zhu Y<sup>1</sup>, Fang Y<sup>2</sup>, McCollam PL<sup>3</sup>

<sup>1</sup>Eli Lilly and Company, Indianapolis, IN, USA, <sup>2</sup>PharmaNet/13, Indianapolis, IN, USA, <sup>3</sup>Eli Lilly and Company, Inc., Indianapolis, IN, USA

**OBJECTIVES:** To examine the demographic and clinical characteristics, and cardiovascular treatment in patients with high-risk vascular disease (HRVD). **METHODS:** A large employer-based US administrative claims database was used to conduct this retrospective cohort study. Patients with HRVD (defined as cerebrovascular disease [CVD], coronary artery disease with diabetes [CADD], peripheral artery disease [PAD], or history of acute coronary syndrome [ACS] [≥30days through 365 days after discharge for ACS]) between October 1, 2008 to September 30, 2009, ≥65 years of age, were identified with minimum 12-month pre- and 24-month post-index health plan eligibility. Patients' baseline demographic characteristics, comorbidities, and medication use were examined and compared across groups with and without polyvascular disease. **RESULTS:** There were 525,893 HRVD patients identified with an average age of 77.2 years and gender of 51.0% male. Of the identified patients, 59.5% had hypertension, 32.9% had hypercholesterolemia, and 44.7% had diabetes. Patients were generally undertreated with statins (50.3% HRVD; range: 44.9% PAD to 64.0% CADD), antiplatelets (21.4% HRVD; range: 16.8% CVD to 49.7% ACS), beta-blockers (41.8% HRVD; range: 35.2% CVD to 67.1% ACS), and other evidence-based risk reduction therapies. Patients with >1 affected artery bed (18%) had numerically similar age (age: 77.1, 77.6, 77.0 for 1, 2, 3 affected disease beds), but had higher cardiovascular risk factors (for 1, 2, 3 affected disease beds, hypertension: 57.2%, 69.1%, 73.4%; hypercholesterolemia: 32.0%, 36.6%, 37.3%; diabetes: 40.5%, 61.2%, 83.9%), and used more cardiovascular-related medications (statins: 48.0%, 59.9%, 67.5%; antiplatelets: 18.3%, 33.8%, 48.8%; beta-blockers: 39.0%, 53.3%, 64.4%) compared to patients with only 1 affected disease bed (p<0.01). The average number of medications per patient was 9.1 for HRVD patients, ranging from 7.6 for CVD-alone patients to 17.7 for patients with ACS, CADD, CVD, and PAD (N=1456). **CONCLUSIONS:** In elderly HRVD patients, classic cardiovascular risk factors are consistent and common, but are undertreated in the U.S.

#### PCV142

##### PHYSICIAN'S ADHERENCE TO THE 2009 AHA/ACC GUIDELINES IN ACUTE MYOCARDIAL INFARCTION (AMI) IN CARDIAC CARE UNIT OF A PRIVATE TERTIARY HEALTH CARE SETTING IN NORTHERN INDIA

Sunarkani R<sup>1</sup>, Tiwari P<sup>2</sup>, Malhotra S<sup>3</sup>

<sup>1</sup>National Institute of Pharmaceutical Education and Research, Mohali, India, <sup>2</sup>National Institute of Pharmaceutical Education and Research (NIPER), S.A.S. NAGAR, India, <sup>3</sup>Fortis Hospital, Mohali, Punjab, India

**OBJECTIVES:** Less numbers of studies on cardiovascular diseases were found in Indian population. So, the results of present study may helpful in improving the consistency and quality of care in the management of AMI in Indian population. The objective of this retrospective observational study was to evaluate the physicians' adherence to 2009 American Heart Association (AHA)/American College of Cardiology (ACC) guidelines in the management of AMI. **METHODS:** Chi-Square test and student t-test were used for analysing the data. The adherence to early and late performance measures was assessed by comparing the performance measures actually given to the patients on admission and discharge with those recommended by the AHA/ACC guidelines for management of AMI. **RESULTS:** A total of 127 patients' with confirmed diagnosis of AMI were analysed in this observational study. Statistically significant difference was found between average ages of male and female patients (57.2±1.2, 66±1.7 respectively, P<0.05). The adherence to clinical performance measures like aspirin, antithrombin and thrombolytic therapy on admission and discharge was found to be 100%. Adequate AMI management was seen in 75.9% NSTEMI and 70.4% STEMI patients. No difference in the adequate management for AMI was found between STEMI and NSTEMI groups (P>0.05). Low adherence was seen for the prescription of b-blocker on discharge in both STEMI and NSTEMI patients (83.7%, 86.2% respectively) when compared to other performance measures. The adherence to all early performance measures in both the groups was found to be good. **CONCLUSIONS:** The overall adherence to early and late performance measures in AMI management in this North Indian study population was satisfactory. Adaptation and implementation of clinical practice guidelines in any health care sector will increase the consistency and quality of care.

#### PCV143

##### ANTITHROMBOTIC STRATEGIES IN ACUTE CORONARY SYNDROME AND ATRIAL FIBRILLATION: A COMMUNITY PERSPECTIVE

Chamberlain AM<sup>1</sup>, Gersh BJ<sup>1</sup>, Klaskala W<sup>2</sup>, Mills RM<sup>2</sup>, Alonso A<sup>3</sup>, Weston SA<sup>1</sup>, Roger VL<sup>1</sup>

<sup>1</sup>Mayo Clinic, Rochester, MN, USA, <sup>2</sup>Janssen Research & Development, LLC, Raritan, NJ, USA,

<sup>3</sup>University of Minnesota School of Public Health, Minneapolis, MN, USA

**OBJECTIVES:** Atrial fibrillation (AF) commonly complicates acute coronary syndromes (ACS) and selecting antithrombotic regimen for these patients is complex. We describe the spectrum of antithrombotic use in a community cohort of patients with ACS, and identify predictors of the choice of strategies in

ACS patients with AF. **METHODS:** Olmsted County, Minnesota residents hospitalized with incident myocardial infarction or unstable angina during 2005-2010 were identified and classified according to the presence or absence of AF either prior to or during the index ACS hospitalization. Logistic regression identified factors associated with double/triple versus none/single antithrombotic therapy in those with AF. **RESULTS:** Of 1108 incident ACS patients, 229 (20.7%) had concomitant AF (ACS+AF). Only 15.7% ACS+AF patients underwent percutaneous interventions (PCI) in contrast to 35.4% ACS patients without AF having PCI. AF substantially impacted the choice of antithrombotic strategy at discharge. Nearly half (49.3%) of the ACS+AF patients were discharged on either two or three antithrombotic agents; 39.3% received aspirin only. One-third (33.6%) of those with ACS+AF received warfarin, mostly in combination

with a single antiplatelet, and 10.0% of patients received warfarin with two antiplatelet agents. In contrast, among ACS patients without AF, 63.5% were discharged on either two or three agents, the majority on dual antiplatelets, with only 3.8% on warfarin and 1.3% on warfarin with two antiplatelets. After adjustment for age and sex, the predictors of double/triple agent treatment strategies in ACS+AF patients included higher peak troponin, PCI on index admission, higher body mass index, non-smoking status, hypertension, and higher CHADS<sub>2</sub> score. **CONCLUSIONS:** In the community, AF frequently coexists with ACS. AF, in conjunction with patient-level risk factors, influences the choice of antithrombotic agents in ACS patients. These observational data underscore the importance of ACS+AF and the need for evidence from randomized trials and observational studies to guide clinical decisions.